## REMARKS

The Official Action of February 17, 2004 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claims 11 and 16 have been amended to correct an obvious typographical error in the formula. Claim 11 has also been amended with respect to dosage amount of the recited compound. Support for the amendment to the dosage amount appears in the specification as filed at, for example, Table 1 on page 18 in conjunction with the paragraph bridging pages 15 and 16. Claims 12 and 13 have been amended to remove the basis for the rejection at paragraph 3 of the Official Action. All claims as amended are respectfully believed to be sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph.

New claims 24-32 have been added more completely to define the subject matter which Applicants regard as their invention. Support for the recitations in claims 24-25 and 27-32 appears, for example, in the specification on pages 14-15 and Table I on page 18, which describes gametocytocidal activity experimentation performed on Rhesus monkeys who were carriers for gametocytes of *P. cynomolgi.* The experimentation shows that the claimed compound of formula (1) kills gametocytes within erythrocytes in blood of the monkeys when the recited compound is administered in a single dose in any of the claimed amounts within a seven day period (see Table 1 on page 18 of the specification). The specification also shows

that the monkeys were not infective even after the seven day period shown in Table I (see specification at page 15, first full paragraph).

Claims 11-18, 22, and 23 were rejected under 35 USC 102(b) as allegedly being anticipated by Puri et al. Claims 11-18, 22 and 23 were also rejected under 35 USC 103(a) as allegedly being unpatentable over Nodiff in view of Paliwal et al and Puri et al. Applicants respectfully traverse these rejections.

With respect to the rejection under 35 USC 102(b) for alleged anticipation, the Examiner does not dispute that the prior art does not show that the claimed compound has gametocytocidal activity, but contends that this activity is inherent in the compound described in the reference. Applicants respectfully note that the Puri et al article presents a comparison between the relative toxicity of compound 80/53 with primaquine. The compound was administered to Beagle dogs for determination of safety profile and not for a determination of anti-relapse activity. Insofar as the reference purports to allege a prior art dose regimen of the 80/53 compound for radical curative activity, it is alleged to be 1.25mg/kg x 7 days (see Puri et al at column 2, first full paragraph).

The dose regimen used for gametocytocidal activity and anti-relapse activity is not the same, as is reflected in the amended claims. The anti-relapse activity treatment referred to in the reference is given for seven consecutive days, whereas the treatment for gametocytocidal activity recited in claims 16-18 and 23-32 is **for a**

**single dose** to sterilize the gametocytes. As described in the specification at pages 14-15 and Table I, a single dosage of 3.75 mg/kg of the claimed compound stops malaria transmission to a vector in five hours by virtue of its gametocytocidal action. With respect to claims 11-15, the recited dosage per day is **below** the daily dosage referred to in the reference. In other words, the dosage regimen recited in all claims as amended is outside of the amounts described in Puri et al and the reference accordingly cannot be said to anticipate the claims as amended, either expressly or inherently, for this reason alone.

With particular respect to claims 25 and 31-32, the reference also cannot be said to anticipate the claims because there is nothing in the reference that would show or suggest that the compound described therein was administered to animals who were carriers of mature gametocytes of a Plasmodium species. A reference cannot be said to anticipate a claim on the basis of inherency unless the reference makes clear that all recited elements were **necessarily** present in the thing described in the reference (see MPEP Section 2131.01). This is not the case.

With respect to the rejection under 35 USC 103(a), the combination of references, even if proper, would not arrive at the claimed invention because it would not provide the claimed dose regimen (as discussed above) and would accordingly not show all of the limitations of the claimed invention for this reason alone. Indeed, the teaching in the Puri et al reference of a daily dose regimen of 1.25 mg/kg x 7 days teaches away from the recitation of **a single dose** in claims 16-18 and 23-32.

In addition to the above, it is respectfully submitted that there would have been no reasonable expectation of success in the use of the claimed compound to provide gametocytocidal activity by virtue of any alleged gametocytocidal activity of primaquine. Puri et al show that compound 80/53 and primaquine have different properties, and in particular that compound 80/53 has a lower toxicity than primaquine. Why then would it have been expected that other properties of primaquine and 80/53 would be the same? To the contrary, Applicants respectfully submit that Puri et al teach away from any such expectation such that the cited references cannot be combined to set forth even a *prima facie* case of obviousness for the invention as claimed.

In view of the above, it is respectfully submitted that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,

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